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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/563,465

01/05/2006

Giuseppe Giannini

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EXAMINER

HAVLIN, ROBERT H

ART UNIT

PAPER NUMBER

1626

NOTIFICATION DATE

DELIVERY MODE

09/03/2009

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

info@lmiplaw.com

<b>Office Action Summary</b>	<b>Application No.</b> 10/563,465	<b>Applicant(s)</b> GIANNINI ET AL.	
	<b>Examiner</b> ROBERT HAVLIN	<b>Art Unit</b> 1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 17 June 2009.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,2 and 5-17 is/are pending in the application.
- 4a) Of the above claim(s) 5-10 and 12-17 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1 and 11 is/are rejected.
- 7) ☒ Claim(s) 2 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 05 January 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

### DETAILED ACTION

**Status of the claims:** Claims 1, 2, and 5-17 are currently pending.

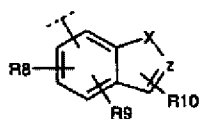
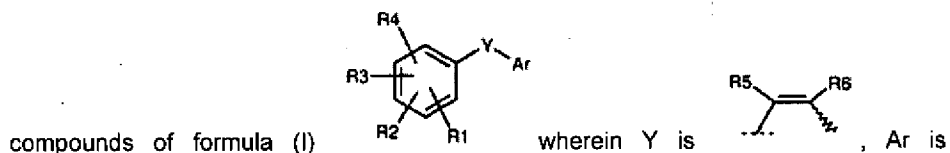
**Priority:** This application is a 371 of PCT/IT04/00373 (7/6/2004).

**RCE:** A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 6/17/09 has been entered.

### Election/Restrictions

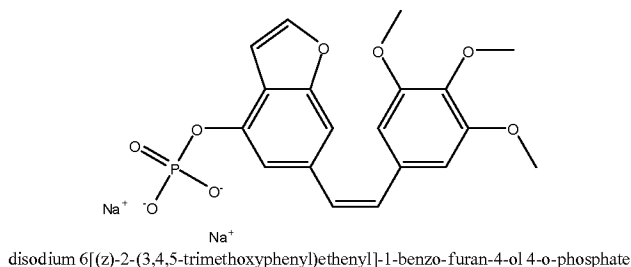
The election is as recited in the previous office action:

Applicants' election of Group (III), claims 1, 2 and 11, with traverse directed to



X is O, Z is CH, and the rest of the variables are as defined in a paper filed 06/25/2007 is acknowledged.

Applicant also elected the following species:



As detailed in the following rejections, the generic claim encompassing the elected species was not found patentable. Therefore, the provisional election of species is given effect, the examination is restricted to the elected species only, and claims not reading on the elected species are held withdrawn. Accordingly, claims 5-10, 12-17 are hereby withdrawn.

Should applicant, in response to this rejection of the Markush-type claim, overcome the rejection through amendment, the amended Markush-type claim will be reexamined to the extent necessary to determine patentability of the Markush-type claim. See MPEP 803.02.

#### **NEW CLAIM REJECTIONS NECESSITATED BY AMENDMENT**

##### ***Claim Rejections - 35 USC § 112***

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1 and 11 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Applicant has added the following new language to claim 1 without identifying where support can be found:

or halogen wherein at least one of R<sub>8</sub>, R<sub>9</sub> and R<sub>10</sub> is OPO<sub>3</sub>H<sub>2</sub> or OCH<sub>2</sub>OPO<sub>3</sub>H<sub>2</sub> and their disodium salt;

The examiner has searched the specification and could not find such language or representative species to support this new subgenus.

***Claim Objections***

Claim 2 is objected to for being dependent on a rejected base claim.

**RESPONSE TO APPLICANT'S REMARKS/AMENDMENTS**

***35 USC § 102 Rejection***

1. Claims 1 and 11 were rejected under 35 U.S.C. 102(b) as being anticipated by US 3697513.

In response, applicant has amended the claims to require “at least one of R8, R9, and R10 is OPO3H2 or OCH2OPO3H2 and their disodium salt;” thereby adding a limitation which was not present in the teachings of the ‘513 patent. Therefore, **this rejection is withdrawn.**

***35 USC § 103 Rejection***

2. Claims 1 and 11 were rejected under 35 103(a) as being unpatentable over US 5,858,995 ("Kawai").

In response, applicant has amended the claims to require “at least one of R8, R9, and R10 is OPO3H2 or OCH2OPO3H2 and their disodium salt;” thereby adding a limitation which was not present in the teachings of the ‘995 patent.

In addition, applicant argues that the compounds of Kawai are not enabled for the teaching of bone cancer in the specification because the needed experimentation would be undue and unreasonable. This argument is not persuasive because the issue is not whether the prior art enabled for treating bone cancer, but whether Kawai is a

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sufficiently analogous art such that one of ordinary skill in the art would reasonably be led to pursue improvements in a manner to arrive at the claimed invention.

Furthermore, MPEP 2121.01 clearly states:

"Even if a reference discloses an inoperative device, it is prior art for all that it teaches." Beckman Instruments v. LKB Produkter AB, 892 F.2d 1547, 1551, 13 USPQ2d 1301, 1304 (Fed. Cir. 1989). Therefore, "a non-enabling reference may qualify as prior art for the purpose of determining obviousness under 35 U.S.C. 103." Symbol Techs. Inc. v. Opticon Inc., 935 F.2d 1569, 1578, 19 USPQ2d 1241, 1247 (Fed. Cir. 1991).

Thus applicants assertion that the disclosure Kawai needs to be enabling for the treatment of bone cancer for consideration in an obviousness determination is not persuasive.

Nevertheless, **this rejection is withdrawn** is withdrawn because the claims no longer possess substantial structural similarities as a result of the amendments discussed above.

### ***Objections***

The objection to claim 2 cited in the prior office action is withdrawn based on applicant's amendments.

### ***Conclusion***

The claims are not in condition for allowance.

### ***Correspondence***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ROBERT HAVLIN whose telephone number is (571)272-9066. The examiner can normally be reached on Mon. - Fri., 7:30am-5pm EST.

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If attempts to reach the examiner by telephone are unsuccessful the examiner's supervisor, Joe McKane can be reached at (571) 272-0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Robert Havlin/  
Examiner, Art Unit 1626